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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,013	06/27/2003	Gregory R. Whittaker	022956-0216	8344
21125	7590	07/27/2005	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			ARAJ, MICHAEL J	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/609,013	WHITTAKER ET AL.
	Examiner	Art Unit
	Michael J. Araj	3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 27 June 2003.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-19 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 27 June 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/29/03.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "16" has been used to designate both "the base portion" and "the arm portion" as seen in Figure 1A and Figure 1B, respectively. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to because reference character "36" is not clear to what it is pointing to. It appears to be pointed to the guide member identified by character "50". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If

a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The disclosure is objected to because of the following informalities:

Reference character "14" has been used to identify both "the arm portion" and "the base portion", page 7 line 26.

Appropriate correction is required.

### ***Claim Objections***

Claim 3 is objected to because of the following informalities: Claim 3 states, "having a pointed proximal end, a distal end". This does not appear to correlate with the subject matter stated in the specification. It is assumed that the applicant meant "having a proximal end, a pointed distal end" and will be considered as such for examination purposes. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-13 and 15-19, as understood, are rejected under 35 U.S.C. 102(e) as being anticipated by Whitaker et al. (U.S. Patent No. 6,517,546)

The applied reference has a common utility with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Whitaker et al. (U.S. Patent No. 6,517,546) discloses an adjustable drill guide comprised of a guide frame having an arm portion (20) and transverse base portion (15), a cannulated rod member (40) connected to the base portion and parallel to the arm portion further having an elongated stem portion (25), and a guide member (58) including a channel (60) extending therethrough at an angle normal to the longitudinal axis of the arm as well as being moveable and lockable along the length of an arm

portion. The rod member also includes an enlarged head (30) have an aperture sized to receive a removable trocar sleeve.

Whitaker et al. also discloses a method for fixing a tissue graft within a bone tunnel that include preparing a bone tunnel for insertion of a tissue graft with the aforementioned adjustable drill guide, forming a bore transverse to the bone tunnel at a location near the bone tunnel exit, placing the tissue graft inside the bone tunnel and securing the tissue graft within the bon tunnel at the location of the bore. This method further includes placement of the elongated step portion into the bone tunnel, locking the guide member, inserting a drill bit through the bore of the guide member where drilling will commence so that it extends transversely through the bone tunnel and repeating this to administer another hole. The method further includes placing a cross pin though the bore to compress the tissue graft within the bone tunnel near the bone tunnel exit, securing the tissue graft further using a graft attachment device, and anchor the graft attachment device to a portion of the bone outside the bone tunnel.

Claims 1, 3-13 and 15-19, as understood, are rejected under 35 U.S.C. 102(b) as being anticipated by McKernan et al. (U.S. Patent No. 6,066,173).

McKernan et al. (U.S. Patent No. 6,066,173) discloses an adjustable drill guide comprised of a guide frame having an arm portion (106) and transverse base portion (104), a cannulated rod member (16) connected to the base portion and parallel to the arm portion further having an elongated stem portion (133), and a guide member (120) including a channel (72) extending therethrough at an angle normal to the longitudinal axis of the arm as well as being moveable and lockable along the length of an arm

portion. The rod member also includes an enlarged head (20) have an aperture sized to receive a removable trocar sleeve.

McKernan et al. also discloses a method for fixing a tissue graft within a bone tunnel that include preparing a bone tunnel for insertion of a tissue graft with the aforementioned adjustable drill guide, forming a bore transverse to the bone tunnel at a location near the bone tunnel exit, placing the tissue graft inside the bone tunnel and securing the tissue graft within the bon tunnel at the location of the bore. This method further includes placement of the elongated step portion into the bone tunnel, locking the guide member, inserting a drill bit through the bore of the guide member where drilling will commence so that it extends transversely through the bone tunnel and repeating this to administer another hole. The method further includes placing a cross pin though the bore to compress the tissue graft within the bone tunnel near the bone tunnel exit, securing the tissue graft further using a graft attachment device, and anchor the graft attachment device to a portion of the bone outside the bone tunnel.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected, as understood, under 35 U.S.C. 103(a) as being unpatentable over McKernan et al. (U.S. Patent No. 6,066,173) in view of Goble et al. (U.S. Patent No. 5,350,380).

McKernan et al. discloses an adjustable drill guide for forming a transverse bore through a bone tunnel of a bone. The claimed invention is disclosed except for the arm portion that includes indicia representing the relative height of the channel with respect to the bone tunnel when the elongated stem portion is inserted inside the bone tunnel. Goble et al. (U.S. Patent No. 5,350,380) teaches a body portion of drill guide apparatus that has markings for a measurement scale with the drill sleeve in reference to another axis (e.g. the trocar entry point in reference to the opening of the bone tunnel when the elongated stem portion is inserted inside the bone tunnel.) It would have been obvious to one skilled in the art at the time the invention was made to construct the drill guide of McKernan et al. with indicia on the arm in view of Goble et al., in order to measure the relative height of the channel with respect to the bone tunnel.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the bore extend transversely through the bone tunnel at a distance between about 3 to 5 mm from the bone tunnel entrance since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-982 for prior art of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Araj whose telephone number is 571-272-5963. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
MJA

  
EDUARDO C. ROBERT  
PRIMARY EXAMINER